

REVISED FIP BASEL STATEMENTS ON THE FUTURE OF HOSPITAL PHARMACY

国际药学联合会（FIP）关于医院药学未来发展的巴塞尔声明修订版

Since the original Basel Statements on the Future of Hospital Pharmacy were released in 2008, the Statements have been used worldwide to guide the development of practice in hospital pharmacy. This revision was developed by the FIP Hospital Pharmacy Section in 2014, and was approved Bangkok, Thailand in September 2014. The final revised Statements were released on 10th September 2015. For more information about the Basel Statements, the FIP Hospital Pharmacy Section and FIP, please see <http://www.fip.org/basel-statements>.

关于医院药学未来发展的巴塞尔声明自 2008 年发布以来，一直在世界各地为医院药学实践的发展提供指导。本次修订于 2014 年由国际药学联合会（FIP）医院药学工作组完成，并于同年 9 月在泰国曼谷召开的国际药学大会上获得批准。最终修订版本已于 2015 年 9 月 10 日发布。如需了解巴塞尔声明、国际药学联合会医院药学工作组以及国际药学联合会的更多信息，请访问 <http://www.fip.org/basel-statements>。

Overarching and Governance Statements

总则

1. The overarching goal of hospital pharmacists is to optimize patient outcomes through collaborative, inter-professional, responsible use of medicines¹ and medical devices.

1. 医院药师的终极目标是通过协作的、跨领域的和尽责的使用药物及医疗器械来最优化患者的治疗结果。

The responsible use of medicines means:

药物尽责使用的含义是：

- That a medicine is only used when necessary and that the choice of medicine is appropriate based on what is proven by scientific and/or clinical evidence to be most effective and least likely to cause harm. This choice also considers patient preferences and makes the best use of limited healthcare resources.
- 仅在必要时才使用药物，药物选择须建立在经科学和/或临床证据证明其效果最佳、毒副作用最小的基础之上。这种选择还需要考虑患者意愿，并能使有限的医疗资源得到最佳利用。
- There is timely access to and the availability of quality medicine that is properly administered and monitored for effectiveness and safety.
- 能及时获取并能使用其有效性和安全性得到正规监控的质量合格的药品。
- A multidisciplinary collaborative approach is used that includes patients and those in addition to health professionals assisting in their care.
- 所谓采用跨领域协作的方式，须包括患者以及健康专业工作者以外为患者提供帮助的人员。

2. At a global level, evidence-based hospital pharmacy practice standards should be developed. These should assist national efforts to define standards for the extent and scope of hospital pharmacy services and should include corresponding human resource and training requirements.

2. 应在全球层面制定循证的医院药学实践规范。这些规范将帮助不同国家来确定其医院药学服务的广度与深度标准，还应包括与之相适应的人力资源和培训要求。

3. Hospital pharmacists should engage health authorities and hospital administrators to ensure appropriate resources for, and design of, the hospital medicines-use process.

3. 医院药师应参与卫生行政主管部门及医院管理部门的工作，以确保医院药品使用流程得到适当的资源和合理的设计。

4. Health authorities should ensure that each hospital is serviced by a pharmacy that is supervised by pharmacists who have completed advanced training in hospital pharmacy.

4. 卫生行政主管部门应确保每个医院都应该有一个由药师管理的药学部门，而药师则应该接受过医院药学的高级培训。

5. The Chief Pharmacist/Director of Pharmacy should be the **accountable** professional coordinating the responsible use of medicines¹ in the hospital.

5. 医院药学部门主管/科主任应该是负责协调医院内药物尽责使用的专业负责人。

6. Hospital pharmacists should serve as a resource regarding all aspects of medicines use and be accessible as a point of contact for **patients and** health care providers.

6. 医院药师成为所有与药物使用相关问题的一大资源，并成为患者与医务人员随时可以沟通的联系纽带。

7. All prescriptions should be reviewed, interpreted, and validated by a hospital pharmacist prior to the medicine being dispensed and administered.

7. 所有的处方，都必须由医院药师审核、解读和认可之后才能调配及给药。

8. Hospital pharmacists should monitor patients taking medicines to assure patient safety, appropriate medicine use, and optimal outcomes **for inpatients and outpatients**. When resource limitations do not permit pharmacist monitoring of all patients taking medicines, patient-selection criteria should be established to guide pharmacist monitoring.

8. 医院药师应对用药患者提供监护，确保住院患者和门诊患者的安全、正确使用药物，达到最佳治疗效果。如果因资源有限而致使药师无法覆盖所有患者，则应制定患者选择标准来指导药师选择监护对象。

9. Hospital pharmacists should be allowed to access **and document in** the full patient record.

9. 应给予医院药师查看完整病历并在其中书写的权限。

10. Hospital pharmacists should ensure that patients or care givers are educated and provided written information on the appropriate use of medicines.

10. 医院药师需要对患者或者监护人进行用药教育，并提供合理用药的书面材料。

11. Hospital pharmacists should provide orientation, drug information and education to nurses, physicians, and other hospital staff regarding best practices for medicines use (a best practice is a method or technique that has consistently shown results superior to those achieved with other means, and that is used as a benchmark).

11. 医院药师应为护士、医生和其它医务人员提供关于药物使用最佳实践相关的指导、药物信息和教育（最佳实践是指与其他方法相比，能持续显示出更优效果的方法或技术，且已经成为规范）。

12. Undergraduate pharmacy curricula should include hospital-relevant content, and post-graduate training programs and specializations in hospital pharmacy should be developed.

12. 药学专业的本科课程中应纳入医院相关的内容，应设置医院药学毕业后教育课程和专科培训项目。

13. Hospital pharmacists should actively engage in research into new methods and systems to improve the use of medicines and of human resource needs in hospital pharmacy.

13. 医院药师应积极参与新方法和新体系的研究，从而优化医院药学部门的药物使用和人力资源配置。

14. Hospital pharmacists should take responsibility for the management and disposal of waste related to the medicine use process, and advise on disposal of human waste from patients receiving medicines.

14. 医院药师应负责管理和处置与药物使用过程相关废弃物，并对因患者用药所致废弃物的处理提供指导。

15. Hospital pharmacists should take responsibility for all aspects of selection, implementation and maintenance of technologies that support the medicine use process, including distribution devices, administration devices and other equipment.

15. 医院药师应负责支持药品使用过程中各种技术的选择、使用和维护等各个环节，包括调配设备、给药装置以及其他设备。

16. Hospital pharmacists must ensure proper storage to maintain the integrity of medicines across the supply chain to ensure quality, safety and security.

16. 医院药师必须确保药品的合理贮存，保持整个供应链中药品的完整性，从而确保药品的质量、安全性与可靠性。

17. Hospital pharmacists should ensure appropriate assessment, development, implementation and maintenance of clinical decision support systems and informatics that guide therapeutic decision making and improve the medicine use process.

17. 医院药师应对临床决策支持系统及信息学进行合理的评估、开发、实施和维护，以指导治疗决策、优化药品使用过程。

18. Each pharmacy should have contingency plans for medicine shortages and emergencies.

18. 每个药学部门都应建立药品短缺和突发事件的应急预案。

19. The “seven rights” (right patient, medicine, dose, route, information, documentation and time) should be fulfilled in all medicine-related activities in the hospital.

19. 医院内所有与药品使用有关的环节都应当遵循“七个正确”原则（正确的患者、正确的药品、正确的剂量、正确的给药途径、正确的药物信息、正确的文档记录以及正确的用药时间）。

Theme 1 – Procurement

主题 1——医院药师与采购

20. Hospital pharmacists should be involved in the complex process of procurement of medicines and health products, promoting equity and access. They should ensure transparent procurement processes are in place in line with best practice and national legislation, are free from conflict of interest, and are based on the principles of safety, quality and efficacy.

20. 医院药师应参与到药品和医疗用品的采购过程中，以促进公平性和可及性。药师应遵循安全、优质和有效的原则，确保采购流程公开透明，符合最佳实践和国家法律，并且没有利益冲突。

21. Procurement practices must be supported by strong quality assurance principles, regularly reviewed and adapted to fit different settings and emerging needs in the most appropriate and cost effective way.

21. 采购过程必须有可靠的质量保证体系作为支持，并进行定期审查和调整，使其满足不同医疗场所或突发事件的需求，并保持最为适当与最佳成本效益比。

22. Procurement should not occur in isolation, but rather be guided by the formulary selection process. This includes the procurement of standard concentrations of high-risk medicines including electrolytes.

22. 药品采购不应单独进行，而应受处方集遴选程序指导，包括标准浓度的高危药品的采购（如电解质溶液）。

23. Procurement must be supported by a reliable information system that provides accurate, timely, and accessible information.

23. 药品采购必须有可靠的信息系统支持，以获得准确、及时和便捷的信息。

Theme 2 - Influences on Prescribing

主题 2——医院药师对处方的影响

24. Hospitals should utilize a medicine formulary system (local, regional, and/or national) linked to standard treatment guidelines, protocols, and treatment pathways based on the best available evidence.

24. 医院应使用与标准治疗指南、方案和治疗路径相符，且具有最优证据的药品处方集系统(地方性、地区性和/或全国性的)。

25. Hospital pharmacists should be **key** members of pharmacy and therapeutics committees to oversee all medicines management policies and procedures, including those related to off-label use and investigational medicines.

25. 医院药师应作为药事管理与药物治疗委员会的核心成员，负责审查所有药品管理政策和规定，包括超说明书用药和临床试验用药方面。

26. Hospital pharmacists should have a key role in educating prescribers at all levels of training on the access to and evidence for **responsible** use of medicines, including the required monitoring parameters and subsequent prescribing adjustments.

26. 医院药师应在各个层级的培训中对处方者的教育方面发挥关键作用，使他们掌握药物尽责使用的原则和证据，包括必要的指标监测和相应的处方调整。

27. Hospital pharmacists should be an integral part of **the multidisciplinary team responsible for therapeutic decision making in all patient care areas.**

27. 医院药师应在所有患者关怀领域中都成为多学科治疗决策团队的必要成员。

28. **Hospital pharmacists should promote seamless care by contributing to the** transfer of information about medicines whenever patients move between **and within health care settings.**

28. 无论患者在不同医疗机构之间或在同一医疗机构内部转移时，医院药师都应该及时交接患者用药信息，促进患者获得无缝的关怀。

29. **Appropriately trained and credentialed hospital pharmacists should participate in** collaborative prescribing.

29. 接受过相应培训并获得相关资质的药师应参与到合作处方活动中。

Theme 3 - Preparation and Delivery

主题 3——医院药师与药品配制和配送

30. Hospital pharmacists should assume responsibility for storage, preparation, dispensing, and distribution of **all medicines**, including investigational medicines.

30. 医院药师应负责所有药品、包括临床试验用药品的贮存、配制、调剂和发放

31. Hospital pharmacists should assume responsibility for the appropriate labeling and control of medicines stored throughout the **facility**.

31. 医院药师应负责所有药品标签正确和医院内药物贮存管控。

32. Hospital pharmacists should be **involved** in determining which medicines are included in ward stock and standardizing the storage and handling of ward medicines.

32. 医院药师应参与制定病房的基数药品目录，并规范这些药品的贮存和管理。

33. Hospital pharmacists should ensure that compounded medicines are consistently prepared to comply with quality standards. **This includes taking responsibility for ensuring medicines not commercially available in a suitable formulation are prepared to accepted practice standards, and ensuring that injectable admixture services comply with accepted practice standards.**

33. 医院药师应确保药品的配制过程一致可控，符合质量标准。这就包括药师必须确保尚无市售剂型药品的配制需要符合公认的操作规范，确保注射用混合配置服务符合公认的操作标准。

34. The preparation of hazardous medicines including cytotoxics should be under the **responsibility of the hospital pharmacist** and prepared under environmental conditions that minimize the risk of contaminating the product and environment, as well as minimizing exposure of hospital personnel to harm **using accepted practice standards.**

34. 危险药品（包括细胞毒性药品）的配制必须由医院药师在适当的环境条件下进行，并且需要满足相关的实践标准，以使药品与环境污染和医院员工药品暴露的风险降至最低。

35. Hospital pharmacists should implement evidence-based systems or technologies (e.g., automated prescription-filling, unit dose distribution, machine-readable coding systems, etc.) to decrease the risk of medication errors.

35. 医院药师应使用有证据支持的系统或技术（如自动化处方调配、单剂量摆药和机读码系统等）来降低用药差错的风险。

36. Hospital pharmacists should support the development of policies regarding the use of medicines brought into the hospital by patients, including the evaluation of appropriateness of complementary and alternative medicines.

36. 医院药师应协助完善患者在院内使用自备药的政策，包括评估使用补充和替代治疗药品的合理性。

37. Hospital pharmacists should implement systems for tracing medicines dispensed by the pharmacy (e.g., to facilitate recalls, etc.).

37. 医院药师应建立已调配发放药品的跟踪系统（例如药品召回等）。

38. Concentrated electrolyte products (such as potassium chloride and sodium chloride) and other institutionally-identified high-risk medicines should be dispensed in ready-to-administer dilutions, and stored in secure, separate areas with distinct labels.

38. 浓缩的电解质药品（如氯化钾和氯化钠）以及其他高危药品必须稀释至可直接使用的溶液形式后方能发放，并应存放在具有醒目的标签标记的安全、隔离区域。

39. Hospital pharmacists should develop simple, rules-based approaches to advancing patient safety; for example, when a large number of dosage units are needed to give a dose (more than two tablets, vials, etc.), the prescription should be verified prior to preparation or dispensing.

39. 医院药师应制定简单、标准化的操作程序来促进患者用药安全。例如，需一次性给予大量的制剂单位时（如同一药品的单次给药量超过两片片剂、两瓶液体等），在调配或发药之前必须要认真核对方。

Theme 4 – Administration

主题 4——医院药师与给药

40. Hospital pharmacists should ensure that the information resources needed for safe medicines preparation and administration are accessible at the point of care.

40. 医院药师应确保在任何提供医学关怀的场所能够随时获得药物安全调配和使用所需的信息资源。

41. Hospital pharmacists should ensure that clinically relevant allergies, drug interactions, contraindications, past adverse events and other relevant medication history details are accurately recorded in a standard location in patient records and evaluated prior to medicine use.

41. 医院药师应确保所有临床相关的过敏情况、药物相互作用、禁忌证、既往药物不良事件以及其他用药史详情都会在病历中规定的位置有准确的记录，且在给药前评估相关信息。

42. Hospital pharmacists should ensure that medicines are packaged and labeled to ensure identification and to maintain integrity until immediately prior to administration to the individual patient.

42. 医院药师应确保药品有包装和标签以确保易于识别和在给患者服药前应保持其包装完整。

43. Medication labels should be clear and have sufficient information to ensure safe administration, including at least 2 patient identifiers, the name of the medicine, prescribed route, dose in mass and, where appropriate, volume and rate of administration.

43. 药品标签应清晰、内容充分，以确保给药安全，标签的内容应包含：至少 2 种患者识别方式、药品名称、给药途径、给药剂量或体积以及药品的给药速率。

44. Hospital pharmacists should ensure that health care professionals who administer medicines are appropriately trained in their use, hazards, and necessary precautions.

44. 医院药师应确保给药的医务人员接受过药物使用、危险性及注意事项等方面的适宜培训。

45. Doses of chemotherapy and other institutionally-identified high-risk medicines should be independently checked against the original prescription by at least two health care professionals, 1 of whom should be a pharmacist, prior to administration.

45. 在化疗药和其它高危药品给药前，至少应有两名医务人员（其中一名应是药师）分别核对原始处方。

46. Hospital pharmacists should develop and implement policies and practices that prevent route errors. Examples include:

46. 医院药师应制定并实施防止给药途径错误的相关政策和规范。例如：

- Labeling of intravenous tubing near insertion site to prevent misconnections;
- 在静脉输液管进针处附件加上标注以防止连接错误；
- Use of enteral feeding catheters that cannot be connected with intravenous or other parenteral lines;
- 肠内营养管不得与输液管或其他管路相连；
- Packaging vinca alkaloids to prevent inadvertent intrathecal administration;
- 将长春碱类药物进行特殊包装以防粗心时鞘内给药；
- Use of oral syringes that are distinctly different from hypodermic syringes to prevent injection of enteral or oral medicines.
- 用于口饲的注射器应当明显区别于皮下注射器，以防止把肠道给药或者口服药品用于皮下注射。

47. Hospital pharmacists should ensure the development of quality assurance strategies for medicines administration to detect errors and identify priorities for improvement.

47. 医院药师应负责制订给药的质量保证策略，以发现用药差错并确定优化重点。

48. The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated.

48. 药师应对给药的整体流程进行设计，取消原始处方和给药记录间的处方转抄步骤。

Theme 5 - Monitoring of Medicines Use

主题 5——医院药师与用药监测

49. An easily accessible reporting system for defective medicines should be established and maintained. Reports of defective or substandard medicines should be reviewed internally and sent in a timely manner to regional or national pharmacovigilance or regulatory reporting programs, and the manufacturer.

49. 应当建立并维护便捷的不合格药品报告系统。将不合格药品的情况进行内部评估，并及时上报地区或全国药物警戒系统、监管报告系统和生产厂商。

50. An easily accessible reporting system for adverse drug reactions should be established and maintained. Reports of reactions should be reviewed internally and sent in a timely manner to regional or national pharmacovigilance or regulatory reporting programs. These data should be regularly reviewed to improve the quality and safety of medicines use practices.

50. 应建立并维护便捷的药品不良反应报告系统。将不良反应的情况进行内部评估，并及时上报地区或全国药物警戒系统、监管报告系统。应定期检查以上数据以确保药物使用的质量和安全。

51. An easily accessible, non-punitive reporting system for medication errors, including near misses, should be established and maintained. Reports of medication errors should be reviewed internally and sent to regional or national medication error reporting or regulatory programs. These data should be regularly reviewed to improve the quality and safety of medicines use practices.

51. 应建立并维护便捷、非惩罚性的用药差错（包括未遂事件）报告系统，将用药差错的情况进行内部评估，并上报地区或全国药物警戒系统。应定期回顾以上数据以确保药物使用的质量和安全。

52. Medicines **use** practices should be self assessed and compared with **benchmarks** and best practices to improve safety, clinical effectiveness, and cost-effectiveness.

52. 应对医院药品的使用情况进行自我评估，通过与标准和最佳实践比较来提升用药的安全、临床有效性和成本效益比。

53. The medicines **use process** should be reviewed through an external accreditation or quality **improvement** program. Hospitals should act on reports to improve the quality and safety of their practices.

53. 应对医院药品使用的流程通过外部质量认证或质量提升计划来进行检查。医院应根据反馈进行整改以提高相关流程的质量和安全性。

54. Pharmacists' clinically-**relevant activities** should be documented, **collected and analyzed** to improve the quality and safety of medicines use and **patient outcomes**. **Activities which significantly impact individual patient care** should be documented in the patient record.

54. 应对药师的临床相关活动进行记录、收集和分析，以改善用药的质量、安全性和患者结果。对患者照护有显著影响的干预措施应在病历中记录下来。

55. **Systematic approaches** (e.g., trigger tools) should be used to provide quantitative data on adverse drug events **and optimal medicines use**. These data should be regularly reviewed to improve the quality and safety of medicines practices.

55. 应该使用系统性的方法（例如预警工具）来提供医院内药物不良事件与合理用药的量化数据。应对以上数据进行定期评估以改善医疗的质量和安全性。

Theme 6 - Human Resources, Training and Development

主题 6——医院药师与人力资源配置、培训和发展

56. At a national level, competency frameworks are defined, established and regularly assessed.

56.在国家层面，应定义、建立并定期评估药师的职业资质评价体系。

57. At a national level, hospital pharmacists should engage health authorities to bring together stakeholders to collaboratively develop evidence-based hospital pharmacy human resource plans, to support responsible use of medicines including those in rural and remote areas.

57.在国家层面，医院药师应与卫生行政主管部门密切协作，召集所有利益相关方共同制定循证的医院药学人力资源规划，在所有地区（包括农村及偏远地区）推行尽责的药物使用。

58. Hospital pharmacists should work with key stakeholders to ensure that workforce education, training, competency, size, and capacity are appropriate to the scope of services, coverage, and responsibilities of all cadres providing pharmacy services.

58.医院药师应与关键利益相关方协作，确保从业人员具有与服务领域、范围和责任相适应的教育、培训、资质、规模及能力。

59. Hospital pharmacy workforce plans should describe strategies for human resource education and training, recruitment and retention, competency development, remuneration and career progression pathways, diversity-sensitive policies, equitable deployment and distribution, management, and roles and responsibilities of stakeholders for implementation.

59.医院药学部门的人力规划应包括人力资源的教育与培训、招聘与留任、能力提升、薪酬与职业发展、多元化政策、合理的岗位配置与分配、管理以及岗位职责等策略。

60. Hospitals should maintain human resource information systems that contain basic data for planning, training, appraising, and supporting the workforce. Data should be collated at a national level to improve workforce planning.

60. 医院应保有人力资源信息系统，其中包括人员配置、培训、评价和支持的基本数据。以上数据应该在国家层面上进行收集整理，以促进人力资源计划制订。

61. The training programs of pharmacy support staff should be nationally formalized, harmonized, and credentialed within a defined scope of practice.

61. 应在国家层面建立范围明确、正式、统一和经过认证的药学辅助人员培训项目。

62. Hospital human resource policies should be founded in ethical principles, equity and human rights, and be compliant with labor regulations, guidelines, and hospital pharmacy practice standards.

62. 医院的人力资源政策制定符合伦理原则、平等和人权，并应符合相关的劳动法规、指南，以及医院药学实践标准。

63. Hospitals should use the nationally accepted competency framework to assess individual human resource training needs and performance.

63. 医院应使用国家认可的资质评价体系来评估每个员工的人力资源培训需求和绩效。

64. To promote interprofessional education and team-based care, the role of hospital pharmacists, including collaborative prescribing, should be included in the curriculum of other health care professionals, and the roles of other health care professionals should be included in the pharmacy curricula.

64. 为了推进跨学科教育和团队式监护，医院药师的职责包括合作处方模式，应纳入其他医务人员的课程中。同时其他医务人员的职责也应纳入药学人员的课程中。

65. Postgraduate clinical courses should be developed to prepare hospital pharmacists for collaborative prescribing of medicines, including instruction in legal and professional accountability.

65. 应设置毕业后临床教育课程来培养医院药师合作处方的能力，包括法律及专业责任方面的课程。

(Translated by Prof. Zhang Chao, Ms. Dong Shu-jie, Mr. Shi Long-wei, Ms. Li Pu.
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Note: the texts marked in yellow indicated those revised or added compared with the Statement in 2008 version.